K052827

NOV - 1 2005

510(k) Summary

OFFICIAL CONTACT: Lisa A. Ewing
Regulatory Affairs Specialist
MEDRAD, INC.
One Medrad Drive
Indianola, PA 15051
(412) 767-2400 Ext. 3780

CLASSIFICATION NAME: Magnetic Resonance Diagnostic Device
(21 CFR 892.1000, Product Code MOS)

COMMON NAME(S): Magnetic Resonance Coil

PROPRIETARY NAME: MEDRAD 8-Receiver Phased Array Neurovascular Coil for Siemens

PREDICATE DEVICE: MEDRAD 8-Receiver Phased Array Neurovascular Coil (K023569)

INTENDED USE: The MEDRAD Phased Array Neurovascular Coil is a receive-only coil intended to be used with Siemens 1.5T MRI Scanners. The coil will facilitate complete MR imaging, including spectroscopy, of the intracranial/extracranial, neurovascular, skull base and C-spine regions without moving the patient or the coil; i.e., no scan room intervention.

DEVICE DESCRIPTION AND COMPARISON TO UNMODIFIED PREDICATE:

The MEDRAD 8-Receiver Phased Array Neurovascular Coil for Siemens maintains a similar intended use, similar operational parameters, similar labeling and is used in a manner similar to the predicate device.

The following comparison tables identify the similarities and differences between the new device and the predicate device.

Comparison of MEDRAD 8-Receiver Phased Array Neurovascular Coil for GE (Predicate) and MEDRAD 8-Receiver Phased Array Neurovascular Coil for Siemens (Proposed)

Feature	(Predicate) MEDRAD 8-Receiver Phased Array Neurovascular Coil for GE	(Proposed) MEDRAD 8-Receiver Phased Array Neurovascular Coil for Siemens
Coil Type	Phased array receive-only coil.	Phased array receive-only coil.
Region of Interest	Vertex of the skull to the aortic arch	Vertex of the skull to the aortic arch
Compatibility	All phased array GEMS 1.5T Signa Excite platforms with 8-receiver capability. All Signa system pulse sequences and appropriate imaging options.	All phased array Siemens 1.5T platforms with 8-receiver capability. All Siemens system pulse sequences and appropriate imaging options.
Tuning	No external tuning, or matching, is necessary, since the coil is matched to the recommended anatomy of interest.	No external tuning, or matching, is necessary, since the coil is matched to the recommended anatomy of interest.
System Connection	Coil plugs into the GE MRI system by way of the phased array quick disconnect port.	Coil plugs into the Siemens MRI system by way of cable sockets in the patient table.
Imaging Configurations	High resolution head, parallel imaging Fast Brain, Neurovascular, C-Spine (user optional), Volume Neck (user optional), high resolution Head and C-Spine (user optional)	High resolution Head, Neck, or Head + Neck (Full), depending on user-selected coil elements

Comparison of Patient-Contacting Materials in MEDRAD 8-Receiver Phased Array Neurovascular Coil for GE (Predicate) and MEDRAD 8-Receiver Phased Array Neurovascular Coil for Siemens (Proposed)

	(Predicate) MEDRAD 8-Receiver Phased Array Neurovascular Coil for GE	(Proposed) MEDRAD 8-Receiver Phased Array Neurovascular Coil for Siemens
Housing	Housing material is made from polyurethane; fire rated UL 94V-0	Housing material is made from polyurethane; fire rated UL 94V-0
Comfort pad, positioning pads, knee pad	Comfort, positioning and knee pad material is made from polyurethane foam sprayed with a Guardian coating and is fire rated to C-117	Comfort, positioning and knee pad material is made from polyurethane foam sprayed with a Guardian coating and is fire rated to C-117
Table pad	N/A	Table pad material is made from Ethylene Vinyl Acetate foam sprayed with a Guardian coating and is fire rated to C-117

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 1 2005

Ms. Lisa A. Ewing
Regulatory Affairs Specialist
Medrad, Inc.
One Medrad Drive
INDIANOLA PA 15051-0780

Re: K052827
Trade/Device Name: MEDRAD 8-Receiver Phased Array Neurovascular Coil for Siemens
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: October 4, 2005
Received: October 7, 2005

Dear Ms. Ewing:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K052827

Device Name: MEDRAD 8-Receiver Phased Array Neurovascular Coil for Siemens

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lieggood

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K052827